IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC., Plaintiff, vs. DEY, L.P. and DEY, INC., Defendants.	C.A. No. 06-113-JJF CONSOLIDATED
SEPRACOR INC., Plaintiff, vs. BARR LABORATORIES, INC., Defendant.	

BARR'S REBUTTAL MEMORANDUM REGARDING CLAIM CONSTRUCTION

Richard K. Herrmann (#405)
Mary B. Matterer (#2696)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, Delaware 19801
Telephone: (302) 888-6800
Fax: (302) 571-1750
rherrmann@morrisjames.com

George C. Lombardi
Imron T. Aly
Elizabeth H. Erickson
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 558-5600
Fax: (312) 558-5700

Attorneys for Defendant Barr Laboratories, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

INTRODUCTION

Barr's opening brief focused upon the "side effects" claim term, which is found in the asserted '755, '994, '090, and '002 patents. That term should be construed consistent with Sepracor's original January 1990 patent application because that is where Sepracor defined its invention. In that application, Sepracor defined "side effects" as "central nervous system stimulatory effects and cardiac arrhythmia" and "teratogenic effects." (*See* Ex. 7 of Barr's Op. Br., Sepracor's 1/5/90 Application, at 6:14-27.) Sepracor disclosed no other side effects, and therefore the claim term cannot be read to include anything that was identified or disclosed ***years after*** the January 1990 application. Sepracor's attempt to do so by incorporating subsequent disclosures of "hypersensitivity" and "basal calcium levels" should be rejected.

In their opening briefs, Sepracor and Dey dispute additional terms. Barr was unaware that Sepracor intended to propose new constructions for the additional terms, instead of arguing that they did not require any construction. Counsel for Barr had exchanged letters and telephone calls with counsel for Sepracor, with the express aim of learning which claim terms and proposed constructions were actually disputed. Sepracor had said that the claim terms "chronic," "bronchospasm," and "reversible obstructive airway disease" did not require any further construction. (*See* Ex. 26, Aly Letter to Ratliff dated 4/7/08, at 1; *see also* Ex. 27, Aly Letter to Ratliff dated 4/30/08.) In its opening claim construction brief, Sepracor changed positions and argued that the terms do require construction. Sepracor and Dey already dispute these terms. Barr therefore addresses the proper construction of those terms in this brief because it does not agree with Sepracor. Barr believes that the terms should be construed consistent with their use in the specification and prosecution history: "chronic" should mean "prophylactic or periodic," "bronchospasm" should mean "asthma or an asthma attack," and "reversible obstructive airway disease" should also mean "asthma or an asthma attack."

Barr's constructions, along with those argued by Sepracor and Dey, are summarized in the table accompanying this brief and labeled Appendix A.[1]

ARGUMENT

I. THE COURT SHOULD ADOPT BARR'S PROPOSED CONSTRUCTION OF "SIDE EFFECTS"

A. Claim Construction Depends On The Meaning At The Time The Original Application Was Filed

As a matter of claim construction, a patentee can only claim what was known to it and disclosed to the Patent Office. The claim construction inquiry is to determine the meaning claim terms "would have to a person of ordinary skill in the art in question ***at the time of the invention, i.e. as of the effective filing date of the patent application***." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (emphasis added). This has been the standard ever since *Markman*: when construing claims, the issue is "what one of ordinary skill in the art at the time of the invention would have understood the term to mean." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed. Cir. 1995) (en banc). For purposes of claim construction, any new developments and disclosures made after the original filing date cannot be retroactively claimed. *Schering Corp. v. Amgen Inc.*, 18 F. Supp. 2d 372, 391 (D. Del. 1998), *aff'd* 222 F.3d 1347, 1354 (Fed. Cir. 2000).

This same principle was confirmed in *MIT v. Abacus Software*, 462 F.3d 1344 (Fed. Cir. 2006), where the Federal Circuit recognized that "[i]n determining the meaning of a term within the pertinent art, it is appropriate to determine the mode of operation of the device ***at the time the***

[1] Appendix A also corrects a typographical error that was in Barr's opening brief. Although the term "side effects" was correctly defined, the parties do not dispute that the '755 patent refers to side effects "associated with chronic administration," the '994 patent refers to side effects "associated with acute administration" and the '090 and '002 patents refer to side effects "associated with administration" of albuterol. Barr already notified counsel for Sepracor and Dey of this correction.

patent application was filed." *Id*. at 1353 (emphasis added). In *MIT*, the parties disputed whether a "scanner" as used in the patent should refer to the meaning when the patent was filed in 1982, or the meaning the term later acquired years after the patent was filed. *Id*. The district court agreed that the appropriate focus was the time the application was filed, and therefore interpreted "scanner" to refer to 1982-era scanners that required "close proximity," unlike later scanners. *Id*. The Federal Circuit affirmed the decision, recognizing that the proper inquiry is "what was known in the art at the time." *Id*. The law of claim construction is clear: the proper interpretation of a claim term cannot extend beyond what was known and disclosed at the time the original application was filed. *See also On Demand Machine Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1339-40 (Fed. Cir. 2006) (finding term "customer," which was not expressly limited in the specification, still "cannot be of broader scope than the invention that is set forth in the specification").

B. When Sepracor's Original Application Was Filed, "Side Effects" Was Defined As Central Nervous System, Cardiac, And Teratogenic Effects

In this case, Sepracor's effective filing date is January 5, 1990, when it filed the original application from which all of the asserted patents later arose. The time of the invention for purposes of claim construction is therefore January 1990. Sepracor stated in its application that racemic albuterol resulted in certain side effects which could be avoided by using R-albuterol by itself instead. (*See* Ex. 7 of Barr's Op. Br., Sepracor's 1/5/90 Application, at 6:9-17.) Sepracor identified the side effects as central nervous system, cardiac, and teratogenic side effects. (*See* Ex. 7 of Barr's Op. Br., Sepracor's 1/5/90 Application, at 2:6-3:6.) Sepracor listed no other types of side effects in its original application. In particular, Sepracor did not disclose or otherwise identify hypersensitivity or basal calcium levels as potential side effects. The term "side effects" therefore should be construed to mean just what the application said when it

defined the term: "Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects."

In its brief, Sepracor alleges that Barr's proposal "seeks to rewrite the patent claim to be limited to some – but not all – of the illustrative side effects identified in the patent specification." (Sepracor's Op. Br. at 13.) Sepracor is wrong. Barr's proposal does not exclude any side effect that is actually disclosed in the specification. Indeed, the only specific examples that Sepracor identifies as being excluded, those of "excitement" and "hyperkinesia" are examples of "central nervous system" side effects, and Barr's proposal includes "central nervous system" side effects. (Barr's Op. Br. at 11 and n.3.)

Sepracor accurately notes that Barr's proposed construction would exclude "airway hyperreactivity" as a chronic side effect. (Sepracor's Op. Br. at 11, 13.) This construction is correct because "hyperreactivity," also referred to as "hypersensitivity," is not disclosed in the original application, and was not disclosed to the Patent Office as a possible side effect until February 10, 1993, three years after Sepracor's original application. (*See* Ex. 11 of Barr's Op. Br., Sepracor's 2/10/93 Amendment, at 6.) As shown above, the central inquiry in claim construction is to determine what one of ordinary skill would understand "side effects" to include in January 1990, in view of Sepracor's original application. Sepracor does not contend that one of ordinary skill in the art would have known that hypersensitivity could be reduced by using R-albuterol as of January 1990. Hypersensitivity simply did not arise as a possible side effect until years after the original application was filed, and Sepracor cannot take credit for developments that occurred after it filed its patent application. *See, e.g.*, *Schering*, 18 F. Supp. 2d at 391. This same analysis applies to Sepracor's claims related to basal calcium levels as a possible acute side

effect, because basal calcium was not disclosed until six years after the original January 1990 application, as discussed further in Barr's opening brief.[2] (*See* Ex. 16 of Barr's Op. Br., Sepracor's 1/24/96 Interview Summary, at 2-3.)

Contrary to Sepracor's argument, the use of phrases like "for example" in the specification does not change the outcome. Phrases like "for example" cannot trump the requirement that a claim is to be interpreted as of the time of the original application, not based on what was later allegedly discovered or invented. If they did, any written description challenge could always be overcome simply by writing "for example" in a patent specification. That is not the law. The specification can support only what it discloses, it cannot serve as a placeholder for later inventions. *See Medtronic Navigation, Inc. v. Brainlab Medizinische Computersysteme GmbH*, 222 F. App'x 952, 957 (Fed. Cir. 2007) (preventing expansion of claim to unsupported examples since they were "merely 'an attempt to preempt the future before it has arrived.'") (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)). Sepracor's specification disclosed central nervous system, cardiac, and teratogenic side effects. If there happen to be known side effects that fit into these three categories, even if they are not expressly listed, Sepracor would still be able to include them within the scope of its claims. That is why Barr's proposal refers not only to the specific examples, but to the broadest categories that Sepracor actually described in its patent application: central nervous system, cardiac, and teratogenic side effects. Sepracor is not entitled to anything more.

[2] In any event, Barr notes that it will dispute as a factual matter whether or not hypersensitivity and basal calcium are really side effects at all, instead of potential potency issues. (*See* Ex. 13 of Barr's Op. Br., Sepracor's 7/23/99 Amendment, at 3) ("applicants' disclosure does not relate to potency".)

Sepracor erroneously relies on the Examiner's Reasons for Allowance as relevant to claim construction. The Examiner's Reasons for Allowance dealt with questions of prior art, not claim construction:

> Moreover, it is the Examiner's opinion that it would not have been expected from the prior art of record that the R- isomer of albuterol would possess the improved side effect profile as established in the declaration of Dr. Aberg filed July 23, 1993, i.e., that the R- isomer of albuterol does not cause the hypersensitivity reaction normally associated with long-term racemic albuterol administration in patients suffering from asthma. (Ex. 22, 7/26/94 Notice of Allowability, at 3.)

The Examiner was considering here only whether or not the prior art disclosed hypersensitivity, not whether Sepracor's specification adequately disclosed hypersensitivity. Indeed, there was no evaluation during prosecution of whether the January 1990 application disclosed hypersensitivity, nor can one be presumed, because "the PTO does not make such findings as a matter of course in prosecution." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, No. 2007-1265, 2008 U.S. App. LEXIS 7827, *12 (Fed. Cir. Apr. 11, 2008). The Examiner's statement that the prior art did not disclose hypersensitivity as a side effect does not mean that Sepracor's patent did. In fact, Sepracor's specification did not.[3]

C. If Sepracor's Proposed Construction Is Adopted, It Would Render The Asserted Claims Invalid Because Of The Definiteness And Written Description Requirements

As discussed above, Sepracor's claim must be construed in the context of the January 1990 patent application based on what was known and disclosed in that application. Sepracor is not entitled to expand the scope of a claim term to include that which it neither appreciated nor invented as of January 1990, as it seeks to do here. If Sepracor's proposed construction is

[3] If it wished to include later-discovered side effects within the scope of its claims, Sepracor should have filed a new continuation-in-part application to include them as part of its specification. *See PowerOasis*, at *3 and *12 n.4. Sepracor failed to do so.

nonetheless accepted, expanding "side effects" to mean any side effects whether they are identified in the specification or not, then the claims will be rendered invalid due to (1) indefiniteness and (2) the failure to satisfy the written description requirement.

Indefiniteness has been generally discussed in Barr's opening brief. If Sepracor's proposal is accepted, there would be no legitimate basis to draw a line between what types of drug responses are side effects or not. Indeed, as Sepracor now argues, "side effects" should simply mean any side effects known by anyone at any time, ignoring what one of ordinary skill in 1990 would understand the term to mean. This open-ended interpretation would not provide adequate guidance about what is and is not a claimed side effect, thereby rendering the claim term indefinite. *See, e.g.*, *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008).

Moreover, Sepracor's proposal runs afoul of the written description requirement. According to that requirement, this Court noted in *Purdue Pharma* that "the specification must convey with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the invention." *Purdue Pharma, L.P. v. F.H. Faulding & Co.*, 48 F. Supp. 2d 420, 426 (D. Del. 1999). "The policy behind the written description requirement is to prevent overreaching and *post hoc* claims that were not part of the original invention." *Id*. at 427. Sepracor's proposed construction would violate this policy by allowing it to overreach and claim, *post hoc*, side effects that were not part of its original invention. The Federal Circuit affirmed *Purdue Pharma*, recognizing that "one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000). Yet that is exactly what Sepracor is trying to do: based on its disclosure of the forest of "side effects," later pick out the tree of

"hypersensitivity" even though that was nowhere disclosed in the original application. Sepracor's claim construction proposal should therefore be rejected. The term "side effects" in the asserted patent should mean "central nervous system effects (such as tremor, nervousness, shakiness, dizziness, and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects."

II. THE COURT SHOULD ADOPT BARR'S PROPOSED CONSTRUCTION FOR "CHRONIC"

Contrary to Sepracor's assertion, Barr agrees with Dey's proposal for the "chronic" claim term, that it should mean "prophylactic or periodic." The term "chronic" does not appear in the specification, something Sepracor admitted during prosecution. (Ex. 23, 5/11/94 Johnson Decl., at 2.) Thus, the Court must turn to intrinsic evidence for guidance in understanding the meaning of the term as intended by the inventors at the time of filing. *Phillips*, 415 F.3d at 1317. In this case, Sepracor made an argument to the Patent Office about what it meant by the word "chronic." That definition, "prophylactic or periodic," therefore defines the term for purposes of this case.

"Chronic" was first added to an amended claim during prosecution of the '755 patent to obtain patentability. In explaining what it meant by the term "chronic," Sepracor submitted the declaration of Dr. T. Scott Johnson. Through Dr. Johnson, Sepracor asserted that "chronic administration is implicit in the description of modes of administration" in the specification. (Ex. 23, 5/11/94 Johnson Decl., at 2.) Specifically, Sepracor argued that "the person of skill in the art would understand that the application was referring to ***chronic*** therapy when it speaks of ***either prophylactic or periodic*** administration." (*Id*. at 3) (emphasis added.) Following this submission, the Examiner allowed the pending claims in the '755 patent application. (Ex. 22,

7/26/94 Notice of Allowability, at 1-2.) Moreover, the Examiner specifically indicated his reliance on Dr. Johnson's declaration for his allowance of the claims. (*Id*. at 1, 2-3.)

Sepracor said chronic meant "prophylactic or periodic" when it obtained the '755 patent; it cannot change that now in the context of litigation. "Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995). Thus, "explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations…because the public has a right to rely on such definitive statements made during prosecution." *Spectrum Int'l. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed. Cir. 1998) (internal quotations omitted.)

In contrast, Sepracor's proposed construction that chronic should mean "recurring" finds no support in the specification nor the prosecution history. Sepracor instead introduces the term "recurring" as its own interpretation of what Dr. Johnson's declaration said, despite his express use of "prophylactic or periodic." Just as Sepracor defined it during prosecution, "chronic" as found in the '755 patent should be construed to mean "prophylactic or periodic."

III. THE COURT SHOULD ADOPT BARR'S PROPOSED CONSTRUCTION FOR "BRONCHOSPASM" (IN THE '002 PATENT) AND "REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE" (IN THE '993 PATENT)

A. "Inducing Bronchodilation Or Providing Relief Of Bronchospasm" As Found In The '002 Patent Should Mean "Treating Asthma Or An Asthma Attack" Because That Is The Construction Supported By The Specification And Prosecution History

As stated above, claims should be construed to capture what was actually invented and disclosed at the time of the originally-filed patent application. "The scope and outer boundary of claims is set by the patentee's description of his invention," and "the claims cannot be of broader scope than the invention that is set forth in the specification." *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1338, 1340 (Fed. Cir. 2006). In January 1990, when

Sepracor submitted its original patent application, the specification and prosecution history referred to treating "asthma" and "an asthma attack," and therefore this claim limitation should refer to "treating asthma or an asthma attack."

The specification repeatedly refers to asthma and describes bronchospasm as a symptom associated with asthma. (*See* Ex. 1 of Barr's Op. Br., '755 Patent at col. 1, lines 21-22 ("treat bronchial spasms ***associated with asthma***"); col. 1, lines 45-46 ("to reduce bronchial spasms ***associated with asthma***"); col. 1, lines 56-57 ("method for ***treating asthma***"); col. 2, lines 35-36 ("bronchospasm begins in an asthma attack"); and col. 3, line 26 ("effective ***treatment for asthma***") (emphasis added.)) Indeed, even the Abstract for the asserted patents clearly states that "[a] method is disclosed utilizing the optically pure R- isomer of albuterol ***for treating asthma*** while minimizing the side effects associated with albuterol." (*See* Ex. 1 of Barr's Op. Br., '755 Patent Abstract, at 1 (emphasis added.)) Sepracor did not describe conditions other than asthma or an asthma attack, and it therefore cannot now claim the benefit of any other conditions.

The prosecution history also supports Barr's proposed construction. Throughout it, Sepracor focused on albuterol as a treatment of asthma specifically:

- "the thrust of applicants' invention is the treatment of ***asthma***" (*See* Ex. 11 of Barr's Op. Br., Sepracor's 2/10/93 Amendment, at 3 (emphasis added.))
- "the thrust of applicants invention is the reduction of side effects, *which arise in the treatment of* ***asthma***" (*See* Ex. 13 of Barr's Op. Br., Sepracor's 7/23/93 Amendment, at 2 (emphasis added.))
- "Applicants' invention is directed to a method of treating ***asthma***" (*See* Ex. 14 of Barr's Op. Br., Sepracor's 12/7/93 Preliminary Remarks, at 2 (emphasis added.))

There is no support for any condition other than asthma or an asthma attack. Therefore, Sepracor cannot now expand the scope of its claims to cover that which it did not disclose and invent in January 1990, when it filed the original application resulting in the asserted patents.

Sepracor itself recognized in the legal background section of its opening brief that it is the specification and prosecution history that guides claim construction. (Sepracor's Op. Br. at 5-9.) Sepracor went so far as to argue that extrinsic evidence like dictionaries is:

> generally less reliable than the patent itself and the prosecution history in construing claim terms because it is not part of the patent and was not created at the time of the patent prosecution to explain the patent's scope and meaning. (Sepracor's Op. Br. at 9.)

Nevertheless, Sepracor insists that "bronchospasm" in the '002 patent should incorporate a medical dictionary definition, rather than the one set forth in the specification. Its proposed dictionary definition of "contraction of smooth muscle in the walls of the bronchi and bronchioles" is not supported by the patent specification or prosecution history. Moreover, even if Sepracor is allowed to rely on the extrinsic dictionary definition to expand the claims of the '002 patent, the cited dictionary still does not include a phrase added by Sepracor that bronchospasm "is not limited to bronchospasms associated with asthma."

Sepracor argues that the specification is directed to the treatment of "bronchial disorders, such as asthma," because that is what the specification says. (Sepracor's Op. Br. at 20.) The reference to "such as asthma" is explained by the distinction Sepracor made between the long-term condition of "asthma" on one hand, and the shorter-term condition of an "asthma attack" on the other. This observation is found in the prosecution history itself, in the declaration submitted by Dr. Johnson: "To be noted is the distinction between ***asthma*** (a condition or disease state) and ***an asthmatic attack*** (an acute episode of coughing, wheezing or gasping), which often accompanies the general disease state." (Ex. 23, 5/11/94 Johnson Decl., at 2 (emphasis added).) Both are "bronchial disorders," and asthma is an example, but the specification as a whole still does not extend beyond asthma or an asthma attack.

Sepracor resorts to the doctrine of claim differentiation to expand the "bronchospasm" claim term because other patent claims refer to treating "asthma." "However, simply noting the difference in the use of claim language does not end the matter. Different terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper." *Nystrom v. Trex Co., Inc.* 424 F.3d 1136, 1143 (Fed. Cir. 2005). As set forth above, the written description and prosecution history mandate that the term bronchospasm, and thus the phrase "inducing bronchodilation or providing relief of bronchospasm," is limited to treatment of asthma or an asthma attack. Additionally, while it is presumed that claims having different terms have different scope, it is a well-established principle that claim differentiation cannot be used to broaden claims beyond their correct scope. *See Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (upholding the district court's decision not to apply claim differentiation when the patentee had restrictively defined its claims); *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380-81 (Fed. Cir. 2006) (overturning the district court's broad construction of a claim term as inconsistent with the overall context of the invention as described in the specification). The claim term "inducing bronchodilation or providing relief of bronchospasm" should therefore mean treatment of asthma or an asthma attack.

B. "Treating [Or Preventing] Bronchospasm In A Patient With Reversible Obstructive Airway Disease" As Found In The '993 Patent Should Mean "Treating [Or Preventing] Asthma Or An Asthma Attack" Because That Is The Construction Supported By The Specification And Prosecution History

For substantially the same reasons, Barr disagrees with Sepracor and agrees with Dey that the claim terms "treating [or preventing] bronchospasm in a patient with reversible obstructive airway disease" as found in the '993 patent should mean "treating [or preventing] asthma or an

asthma attack." The term "reversible obstructive airway disease" appears for the first time in the application for the '993 patent, and Sepracor asserted that the claims using that term were allowable for the same reasons as the parent applications and resulting patents. (*See* Ex. 20 of Barr's Op. Br., Sepracor's 12/17/99 Preliminary Amendment, at 5.) Because it was newly introduced in 1999, "reversible obstructive airway disease" cannot be used to expand Sepracor's claims beyond what it actually disclosed in its January 1990 application. As stated above, the only conditions described by the patent specification and prosecution history are asthma and asthma attack. *See, e.g.*, *On Demand Mach. Corp.*, 442 F.3d at 1337-38. Therefore, Sepracor is not entitled to claim anything more.

Sepracor proposes to construe "reversible obstructive airway disease" to include a set of diseases "such as asthma, chronic bronchitis, and emphysema." Other than asthma, there simply is no support in the patent or prosecution history for these other disease conditions. Sepracor implicitly admits as much, because it relies for its definition on extrinsic evidence, an article by people other than the named inventors. Sepracor says that it does not really mean to include these other conditions in the scope of its claims, in footnote 14 of its opening brief, but its argument is still that the term should not be limited to asthma. Sepracor's argument should be rejected. As with the "bronchospasm" claim term, even though Sepracor says extrinsic evidence should not be relied upon, it still asks the Court to do just that. Barr's proposed construction should be adopted, and the claim term should be construed consistent with the intrinsic evidence to mean "treating asthma or an asthma attack."

Moreover, closer inspection of the extrinsic journal article upon which Sepracor relies actually supports Dey's and Barr's positions. The Lurie article cited by Sepracor explains that there are no clear-cut definitions between types of "reversible" airway disease: "clear-cut

differentiation between chronic bronchitis, emphysema, and asthma is sometimes impossible." (*See* Ex. 25, Alain Lurie et al., *Long Term Management of Reversible Obstructive Airway Disease in Adults*, Lung, Suppl., at 155 (1990).) Because it is not possible to conclude that chronic bronchitis or emphysema should be included as "reversible" airway disease, even according to Sepracor's own reference, it would be inappropriate to include those diseases within the scope of the claims. Additionally, the Lurie article cites to and relies upon an earlier Morton reference that associates asthma with "reversible obstructive lung disease," while distinguishing other conditions like emphysema as "irreversible or persistent obstructive lung disease." (*See* Ex. 24, James W. Morton et al., *The Reversibility of Chronic Bronchitis, Asthma, and Emphysema*, Dis. Chest, at 126 (1968).) Thus, if Sepracor's extrinsic evidence is relied upon, it further supports Barr's proposed claim construction, and "treating [or preventing] bronchospasm in a patient with reversible obstructive airway disease" as found in the '993 patent should mean "treating [or preventing] asthma or an asthma attack."

IV. THE COURT SHOULD ENTER AN ORDER REGARDING THE TERMS "ACUTE ATTACK," "OPTICALLY PURE," AND "SUBSTANTIALLY FREE" BECAUSE SEPRACOR SAID IT WOULD NOT DISPUTE THEM

Finally, when Sepracor and Barr discussed claim terms to be construed, the parties seemed to agree to the proposed construction of certain additional claim terms. Sepracor's counsel represented that there did not appear to be any dispute, and even asked for a proposed order to be circulated, which Barr sent. (*See* Ex. 26, Aly Letter to Ratliff dated 4/7/08.) These are the claim terms that therefore appear to be agreed, although no stipulation was entered:

CLAIM TERM	CONSTRUCTION
"***optically pure R(-) isomer***" in claim 1 of the '755 patent, claim 1 of the '994 patent, claim 1 of the '090 patent; and "***optically pure R(-) albuterol***" in claims 1, 4, and 10 of the '002 patent and claims 1 and 10 of the '993 patent.	"containing 90% by weight or more of the R(-) isomer" (Ex. 1 of Barr's Op. Br., '755 Patent, col. 2, lines 20-24)
"***substantially free of its S(+) isomer***" in claim 1 of the '755 patent, claim 1 of the '994 patent, and claim 1 of the '090 patent.	"containing 10% by weight or less of the S(+) isomer" (Ex. 1 of Barr's Op. Br., '755 Patent, col. 2, lines 20-24)
"***treating an acute attack of asthma***" in claim 1 of the '994 patent.	"treating an acute attack of asthma (a short and sharp course, not chronic)" (Barr proposed based on Sepracor's interrogatory response, *see* Ex. 27, Tab A.)
"***suffering from an acute attack of asthma***" in claim 1 of the '994 patent.	"while experiencing an asthma attack, an acute episode of coughing, wheezing, or gasping" (Ex. 23, Johnson Decl., at 2.)

Despite later reminders, Sepracor still did not respond about whether to submit a proposed order to the Court to confirm the agreement. Just today, Sepracor even denied having any final agreement. Barr believes that these constructions should be included in a claim construction order because Sepracor has not disagreed with them, and has not proposed alternatives to these proposals.

CONCLUSION

For all the above reasons, Barr respectfully requests that the Court adopt Barr's proposed construction for "side effects," "chronic," "bronchospasm," and "reversible obstructive airway disease." Barr's proposals are found in Appendix A, attached.

Dated: May 1, 2008

/s/ Richard K. Herrmann

Richard K. Herrmann (#405)
Mary B. Matterer (#2696)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, Delaware 19801
Telephone: (302) 888-6816
Fax: (302) 571-1750
Email: rherrmann@morrisjames.com
Email: mmatterer@morrisjames.com

George C. Lombardi
Imron T. Aly
Elizabeth H. Erickson
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 558-5600
Fax: (312) 558-5700
Email: glombardi@winston.com
Email: ialy@winston.com
Email: eerickson@winston.com

Attorneys for Defendant Barr Laboratories, Inc.

APPENDIX A

Parties' Disputed Claim Constructions

'755 PATENT:

Claim Term	Barr's Proposed Construction	Dey's Proposed Construction	Sepracor's Proposed Construction
"side effects associated with chronic administration of racemic albuterol"	"Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." (Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"Reducing those beta-adrenergic side effects, and teratogenic effects associated with the periodic or prophylactic administration of albuterol that are caused directly by the S(+) enantiomer of albuterol." (Dey's Op. Br. at 20.)	"The side effects are those associated with chronic administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 10.)
"chronic administration" and "chronically administering to the individual"	"Prophylactic or periodic treatment." (*See* Barr's Rebuttal Br. at 8.)	"Prophylactic or periodic treatment." (*See* Dey's Op. Br. at 25-26.)	"Plain meaning – to administer the drug to a human on a recurring basis to prevent or reduce the extent to which bronchospasms occur." (Sepracor's Op. Br. at 14.)

Claim Term	Barr's Proposed Construction	Dey's Proposed Construction	Sepracor's Proposed Construction
"while simultaneously reducing undesirable side effects"	"while simultaneously reducing central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." (*See* Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic side effects and teratogenic side effects associated with the use of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol." (Dey's Op. Br. at 20.)	"The side effects are those associated with chronic administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 16.)

'994 PATENT:

Claim Term	Barr's Proposed Construction	Dey's Proposed Construction	Sepracor's Proposed Construction
"side effects associated with the acute administration of racemic albuterol"	"Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with acute administration of racemic albuterol." (*See* Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"Reducing those beta-adrenergic and teratogenic side effects associated with acute administration of racemic albuterol (i.e., treatment with racemic albuterol after onset of an asthma attack) that are directly caused by the S(+) enantiomer." (Dey's Op. Br. at 28.)	"The side effects are those associated with acute administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 17.)
"while simultaneously reducing undesirable side effects"	"while simultaneously reducing central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with acute administration of racemic albuterol." (*See* Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic side effects and teratogenic side effects associated with the [acute] use of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol." (*See* Dey's Op. Br. at 20, 28.)	"The side effects are those associated with acute administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 18.)

'090 PATENT:

Claim Term	Barr's Proposed Construction	Dey's Proposed Construction	Sepracor's Proposed Construction
"side effects associated with the administration of racemic albuterol"	"Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with administration of racemic albuterol." (*See* Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"Reducing those beta-adrenergic side effects and teratogenic effects associated with the administration of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol." (Dey's Op. Br. at 29.)	"The side effects (or adverse effects) are those associated with the administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 18.)
"while simultaneously reducing undesirable side effects"	"while simultaneously reducing central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with administration of racemic albuterol." (*See* Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic and teratogenic effects associated with the use of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol." (*See* Dey's Op. Br. at 30.)	"The side effects (or adverse effects) are those associated with the administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 18.)

'002 PATENT:

Claim Term	Barr's Proposed Construction	Dey's Proposed Construction	Sepracor's Proposed Construction
"inducing bronchodilation or providing relief of bronchospasm"	"Treating asthma or an asthma attack." (Barr's Rebuttal Br. at 10.)	"A method of treating asthma." (Dey's Op. Br. at 31-32.)	"Plain meaning – 'bronchospasm' means a contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen, which is not limited to bronchospasms associated with asthma." (Sepracor's Op. Br. at 19.)
"the concomitant liability of adverse effects associated with racemic albuterol"	"Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with administration of racemic albuterol." (*See* Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"Reducing those beta-adrenergic and teratogenic side effects associated with the administration of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol." (Dey's Op. Br. at 32.)	"The side effects (or adverse effects) are those associated with the administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 18.)

Claim Term	Barr's Proposed Construction	Dey's Proposed Construction	Sepracor's Proposed Construction
"while simultaneously reducing said adverse effects"	"while simultaneously reducing central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with administration of racemic albuterol." (*See* Barr's Op. Br. at 10, citing '755 Patent, col. 3, lines 28-31, 33-35.)	"At the same time the optically pure R(-) isomer is administered in a quantity sufficient to cause bronchodilation there is a reduction in those beta-adrenergic side effects and teratogenic side effects associated with the use of racemic albuterol that are caused directly by the S(+) enantiomer of albuterol." (Dey's Op. Br. at 20, 32.)	"The side effects (or adverse effects) are those associated with the administration of albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification." (Sepracor's Op. Br. at 18.)

'993 PATENT:

Claim Term	Barr's Proposed Construction	Dey's Proposed Construction	Sepracor's Proposed Construction
"treating bronchospasm in a patient with reversible obstructive airway disease"	"Treating asthma or an asthma attack." (Barr's Rebuttal Br. at 13.)	"Treating an asthma patient after the onset of an asthma attack." (Dey's Op. Br. at 33.)	The plain meaning of reversible obstructive airway disease is "a respiratory disorder such as asthma, chronic bronchitis, and emphysema." (Sepracor's Op. Br. at 23.)
"preventing bronchospasm in a patient with reversible obstructive airway disease"	"Preventing asthma or an asthma attack." (Barr's Rebuttal Br. at 13.)	"Chronically treating a patient for asthma." (Dey's Op. Br. at 35.)	The plain meaning of reversible obstructive airway disease is "a respiratory disorder such as asthma, chronic bronchitis, and emphysema." (Sepracor's Op. Br. at 23.)